



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Franco Vallana et al.

Attorney Docket: SBC1025USC1

Serial No.: 10/790,649

Group Art Unit: 3738

Filed: March 1, 2004

Examiner: Suzette Jaime J. Gherbi

For: ANGIOPLASTY STENTS

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed May 15, 2006 from the Final Rejection of claims 1 to 31 of the above-identified application, as set forth in the Final Office Action mailed February 15, 2006. Enclosed is a check in the amount of \$950.00 to cover the fee for filing an appeal brief (\$500.00) and the fee for a two month extension of time (\$450.00). Appellants respectfully request reconsideration and reversal of the Examiner's rejection of the pending claims.

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Date: September 14, 2006

Signature: _____

Name: Jodi Jung

As required by 37 C.F.R. § 41.37, this Brief contains the following items under the headings and in the order suggested therein.

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(1) REAL PARTIES IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Sorin Biomedica Cardio S.r.l.

(2) RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants or Appellants' representative that will have a bearing on the Board's decision in the present appeal.

(3) STATUS OF CLAIMS

Claims 1 to 13 and 29 to 31 are cancelled. Claims 14 to 28 are pending in this application. Claims 14 to 28 are rejected and are the subject of this appeal.

(4) STATUS OF AMENDMENTS

On February 15, 2006, the Examiner issued a Final Rejection. On April 17, 2006, Appellants filed an Amendment and Response in which claims 1, 29 and 31 were amended. In an Advisory Action mailed April 28, 2006, Appellants were notified that the amendments made in the April 17, 2006 Amendment and Response had not been entered. On May 15, 2006, Appellants filed a Supplemental Amendment and Response to Final Office Action in which claims 1 to 13 and 29 to 31 were canceled.

(5) SUMMARY OF INVENTION

The invention as recited in claim 14 relates to a stent 1 for use at an implant site in a vessel. The stent 1 comprises: (i) a radially expandable tubular body and (ii) an active agent for treatment of the implant site (page 4, lines 24 to 26). The tubular body has an interior surface and an exterior surface, and includes a plurality of sinusoidal shaped annular elements 2 and a plurality of connection elements 3 (FIGS. 1 to 4, page 4, lines 26 to 28, and page 7, lines 7 to 10 and 17 to 19). Each annular element 2 is connected to at least one other annular element by at least two connection elements 3 (FIGS. 1 to 4, and page 4, lines 28 and 29). Each connection element 3 has a first end connected to an annular element 2 at a zero point of the sinusoidal shape of the annular element and a second end connected to an adjacent annular element at a zero point of the sinusoidal shape of the adjacent annular element (FIGS. 1 to 4, and page 7, lines 17 to 23). The tubular body has a plurality of recesses 4 containing the active agent (FIGS. 2 to 9, page 4, lines 29 and 30, and page 8, lines 15 to 18). The recesses 4 confer on the elements where they are positioned a hollowed sectional profile of which the recesses 4 occupy a portion of the area of the sectional profile (FIGS. 2 to 9, page 5, lines 1 to 3, and page 14, lines 8 to 14). The geometry of the recesses 4 is such that the bending moments of inertia of the elements containing the recesses are not substantially reduced (page 5, lines 3 and 4).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 14 to 28 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.

Claims 14 to 19 and 22 to 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,758,859 B1 (“Dang”) in view of U.S. Patent No. 6,193,747 B1 (“von Oepen”).

Claims 20 and 21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Dang in view of von Oepen and further in view of U.S. Patent Application Publication No. 2001/0029351 A1 (“Falotico”).

(7) ARGUMENT

A. Rejection Under 35 U.S.C. § 112, First Paragraph

1. Claims 14 to 28

The Examiner rejected claims 14 to 28 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. In particular, the Examiner states that there is no mention in the specification for the limitation of “at a zero point of the sinusoidal shape of the annular element and a second end...at a zero point”.

Appellants’ specification clearly supports the above mentioned limitation. In particular, support can be found in the drawings, specifically FIGS. 1 to 4, and in the specification on page 7, lines 17 to 23, which states that “the connection elements 3 are connected to the cylindrical elements 2 [the annular elements] at the “0” [zero] points of the respective sinusoidal paths [the sinusoidal shape].” Accordingly, Appellants respectfully request the reversal of this rejection of claims 14 to 28.

B. Rejections Under 35 U.S.C. § 103(a)

1. Claims 14 to 19 and 22 to 28 rejected under 35 U.S.C. § 103(a) as obvious over Dang in view of von Oepen

The Examiner rejected claims 14 to 19 and 22 to 28 under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,758,859 B1 (“Dang”) in view of U.S. Patent No. 6,193,747 B1 (“von Oepen”).

Dang in view of von Oepen does not render obvious the claimed invention. Claim 14 is the only remaining independent claim. Claim 14, and claims 15 to 28 which depend therefrom, require that each connection element have a first end connected to an annular element at a zero point of the sinusoidal shape of the annular element and a second end connected to an adjacent annular element at a zero point of the sinusoidal shape of the adjacent annular element. Neither Dang nor von Oepen has this structure. The connecting elements of Dang and von Oepen are connected between peaks and valleys of the sinusoidal annular elements, not at zero points. Accordingly, Appellants respectfully request the reversal of this rejection of claims 14 to 19 and 22 to 28.

2. Claims 20 and 21 rejected under 35 U.S.C. § 103(a) as obvious over Dang in view of von Oepen and further in view of Falotico

The Examiner rejected claims 20 and 21 under 35 U.S.C. § 103(a) as obvious over Dang in view of von Oepen and further in view of U.S. Patent Application Publication No. 2001/0029351 A1 (“Falotico”).

Dang in view of von Oepen and further in view of Falotico does not render obvious the present claimed invention. Claims 20 and 21 require that each connection element have a first end connected to an annular element at a zero point of the sinusoidal shape of the annular element and a second end connected to an adjacent annular element at a zero point of the sinusoidal shape of the adjacent

annular element. Neither Dang nor von Oepen has this structure. The connecting elements of Dang and von Oepen are connected between peaks and valleys of the sinusoidal annular elements, not at zero points. Further, Falotico has no such structure and does not cure this deficiency. Accordingly, Appellants respectfully request the reversal of this rejection of claims 20 and 21.

(8) SUMMARY

For the reasons discussed above, claims 14 to 28 are not properly rejected under 35 U.S.C. § 112, first paragraph, or 35 U.S.C. § 103(a).

Appellants respectfully submit that the written description fully supports the pending claims and that the art cited does not render the claims anticipated or obvious and that the claims are patentable over the cited art. Reversal of the rejections and allowance of the pending claims are respectfully requested.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: September 14, 2006

By Patrick J. O'Connell
Customer No. 009561
Terry L. Wiles (29,989)
Patrick J. O'Connell (33,984)
POPOVICH, WILES & O'CONNELL, P.A.
650 Third Avenue South, Suite 600
Minneapolis, MN 55402
Telephone: (612) 334-8989
Attorneys for Appellants



CLAIMS APPENDIX

Claims 1 to 13 (Canceled).

14. (Previously presented) A stent for use at an implant site in a vessel comprising a radially expandable tubular body and an active agent for treatment of the implant site, the tubular body having an interior surface and an exterior surface, the tubular body including a plurality of sinusoidal shaped annular elements and a plurality of connection elements, each annular element being connected to at least one other annular element by at least two connection elements, each connection element having a first end connected to an annular element at a zero point of the sinusoidal shape of the annular element and a second end connected to an adjacent annular element at a zero point of the sinusoidal shape of the adjacent annular element, the tubular body having a plurality of recesses, the active agent being contained within the recesses, the recesses conferring on the elements where they are positioned a hollowed sectional profile of which the recesses occupy a portion of the area of the sectional profile, the geometry of the recesses being such that bending moments of inertia of the elements containing the recesses are not substantially reduced.

15. (Original) The stent of claim 14 wherein the plurality of recesses are on the exterior surface of the stent.

16. (Original) The stent of claim 14 wherein the hollowed sectional profile of the recesses ranges from 10% to 60% of the area of the sectional profile.

17. (Original) The stent of claim 14 wherein the hollowed sectional profile of the recesses ranges from 20% to 50% of the area of the sectional profile.

18. (Original) The stent of claim 14 wherein the hollowed sectional profile of the recesses is not less than 30% of the area of the sectional profile.

19. (Original) The stent of claim 14 wherein the hollowed sectional profile of the recesses has a C-shaped profile.

20. (Original) The stent of claim 14 wherein the stent has a longitudinal axis and wherein the hollowed sectional profile of the recesses has a rectangular profile, a longer dimension of the rectangular profile extending in a direction tangential to the longitudinal axis of the stent.

21. (Original) The stent of claim 14 wherein the stent has a longitudinal axis and wherein the hollowed sectional profile of the recesses has a rectangular profile, a longer dimension of the rectangular profile extending in a direction radial to the longitudinal axis of stent.

22. (Original) The stent of claim 14 wherein the hollowed sectional profile of the recesses has a substantially U-shaped profile.

23. (Original) The stent of claim 14 wherein the hollowed sectional profile of the recesses has a substantially V-shaped profile.

24. (Original) The stent of claim 14 wherein the hollowed sectional profile of the recesses has undercut areas.

25. (Original) The stent of claim 14 wherein the plurality of recesses is substantially discontinuous.

26. (Original) The stent of claim 14 wherein each recess of the plurality of recesses has a substantially well-shaped configuration.

27. (Original) The stent of claim 14 wherein the active agent comprises at least two different active agents.

28. (Original) The stent of claim 17 wherein the stent has a longitudinal axis and wherein the active agent contained within the recesses is present in a non-uniform distribution along the longitudinal axis of the stent.

29 to 31 (Canceled).

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.